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Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Attn: Phillip L. Chao, Office of Policy and Planning (HF-23)

SUBJECT: Food and Drug Administration
Institutional Review Boards: Registration Requirements
Docket No. 2004N-0242

Dear Mr. Chao:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to offer brief comments on the notice of proposed rulemaking issued by the Food and Drug Administration (FDA), Department of Health and Human Services, regarding registration requirements for institutional review boards (IRBs) involved in reviewing clinical investigations regulated by the FDA. The AAMC represents the nation's 125 allopathic medical schools, over 400 major teaching hospitals and health systems, and more than 105,000 faculty through 94 academic and scientific societies.

AAMC strongly supports the concept of IRB registration and the goal of creating a single registration system for the FDA and the Office of Human Research Protections (OHRP), as well as the FDA's proposed inclusion of accreditation status [56.106(5)] in the IRB registration process.

We support the collection of information by the FDA that aids its efficient enforcement of statutory provisions regarding investigational use of various FDA-regulated products, its enforcement of provisions regarding marketing applications, and its efficient communication with IRBs on various issues. That information includes, in particular, the contact information for the institution operating the IRB and the senior official who is responsible for overseeing IRB activities [proposed section 56.106(1)]; and the IRB's name, address, the name of each IRB chair, and the name of the IRB contact person [56.106(2)].

With respect to 56.106(3), we acknowledge and appreciate that the FDA does not propose that IRBs be required to supply specific numbers of active protocols involving FDA-regulated products undergoing initial and continuing review each year. We have no objection to the proposal of numerical ranges that can be selected by registrants to describe their activity, even though neither actual numbers nor ranges can fully describe the actual workloads of IRBs, as we

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know the FDA appreciates. We also have no objection to the proposed requirement that the IRB describe the types of FDA-regulated products involved in the protocols the IRB reviews, provided that this requirement can be complied with by a simple, generic description (e.g. biological products, color additives, food additives, human drugs, or medical devices) without numerical ranges associated with each product type.

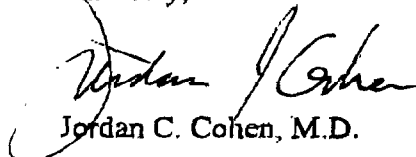
In the information accompanying the proposed registration requirements, the FDA indicates that the information regarding numbers of active protocols reviewed would "enable the FDA to determine how active an IRB is and to assign its inspection resources based on an IRB's activity level." In light of the importance of these proposed uses of the information collected, we note that the data collected are only approximations of actual IRB workloads and must be used carefully and cautiously in evaluating or characterizing IRBs.

As a means of encouraging the use of registration, we note that the FDA proposes to consider sponsors and investigators using an unregistered IRB to be in conflict with their regulatory obligations under part 56. A major issue with any method selected to encourage the use only of registered IRBs is the ability to rely on the accuracy of the web-based information that is to be made available through the registration system. Sponsors and investigators must be able to rely on this information.

We also note that the FDA indicates that it reviewed other options to require sponsors and investigators to use only registered IRBs, for example, refusal to consider information from an application for a research permit for a clinical investigation that is reviewed or is to be reviewed by an unregistered IRB. This option was rejected according to FDA because it equated an IRB that had failed to re-register with a disqualified IRB. The FDA suggests in the supplemental information that the IND regulations might be amended to authorize the FDA to place a study on clinical hold if a sponsor or investigator uses an unregistered IRB. What would the hold mean? If it would mean that the study would be reviewed from that point forward by a registered IRB, this option would be unworkable, because retroactive review of whatever had already occurred would be impermissible under current regulations. The better solution, after ample notice and a suitable grace period, would be for the FDA to refuse to consider information from an application for a research permit that is reviewed or to be reviewed by an unregistered IRB.

We appreciate the opportunity to comment on the proposed single registration process, which has been called for in several recent congressional bills directed at strengthening the protection of human research subjects.

Sincerely,



Jordan C. Cohen, M.D.

cc: David Korn, M.D.
Richard Knapp, Ph.D.